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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,966	12/03/2003	Catherine A. Pipenhagen	47563.0012	4374
57600	7590	10/25/2006	EXAMINER	
HOLLAND & HART LLP 60 E. SOUTH TEMPLE SUITE 2000 SALT LAKE CITY, UT 84111			WOO, JULIAN W	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 10/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/726,966

Applicant(s)

PIPENHAGEN ET AL.

Examiner

Julian W. Woo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 and 42-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22, 25, 28, 31, 33-40, 42, 43, 45 and 46 is/are rejected.
- 7) ☒ Claim(s) 23, 24, 26, 27, 29, 30, 32 and 44 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8/7/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-14, 20, and 34-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With respect to base claims 1 and 34, it is not certain what constitutes an "open rectangle." Is it a sealing plug? How does it provide the frame of reference for measuring surface area-to-volume ratios? Is the "open rectangle" a two-dimensional or a three-dimensional shape? And what are the dimensions of the open rectangle. Also with respect to claim 34, the sealing plug is said to comprise an "open" shape that is compared to an "open rectangle." With respect to claim 20, how does the filament weave through the internal component at "approximately a middle of the external component"?

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 4, and 15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Nash et al. (5,662,681) disclose, in figures 1-3, a tissue puncture closure device and a method of sealing an internal tissue puncture with the device, where the device has a carrier tube (104), a filament (34D), an anchor (32) or internal component, a sealing plug (30) with a high surface-area-to volume ratio or first external component, where the sealing plug comprises a collagen sponge and a generally rectangular shape folded latitudinally, where the sponge is folded twice longitudinally (i.e., compressed in a longitudinal direction), where the sponge is substantially S-shaped (if viewed from a side opposing the view of fig. 3), where the sealing plug fills an internal tissue puncture, where the anchor and sealing plug (or closure device) are inserted into an insertion sheath (100 or 104), and wherein the tissue puncture sealing device is in an undeployed configuration (i.e., the external component is held in a folded configuration by the presence of sutures in the passageway of the external component, so that one portion of the external component is in contact with another portion of the external component at the folds).

5. Claim 28 is rejected under 35 U.S.C. 102(b) as being anticipated by Rousseau (6,425,924). Rousseau discloses, in figures 1-4, a tissue puncture closure device having a filament (22), an anchor (14), a flexible sealing plug (another element 14) with a high surface-area-to volume ratio, where the sealing plug comprises first and second pluralities of openings (the cells of the mesh), and where the filament passes through

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the first plurality of openings through the anchor and back through the second plurality of openings.

6. Claims 43 is rejected under 35 U.S.C. 102(b) as being anticipated by Thal (5,720,765). Thal discloses, at least in figures 5a and 5b, a tissue puncture closure device including an anchor (50 or 58), a sealing plug (54), and a filament (52), where the sealing plug is generally X-shaped in cross-section.

7. Claims 15, 19-22, and 33-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Kensey et al. (5,545,178). Kensey et al. disclose, at least in figures 1-9, a tissue puncture sealing device including an internal component (38), an external component (36) that is folded so that one portion of the external component is in contact with another portion of the external component (see fig. 6), and a filament (42), where the tissue puncture device is in an undeployed configuration; where the external component comprises a filament weave pattern (52), where the filament weaves through a first portion of the filament weave pattern, through the internal component, and back through a second portion of the filament weave pattern (see figs. 6 and 9); where the filament weaves through the internal component at approximately a middle of the internal component (see fig. 6), where first and second portions of the external component comprise two legs of a general V-shape folded latitudinally along a centerline such that the two legs are substantially aligned (see fig. 9), and where the sealing plug is folded from an original V-shape (see fig. 6) to a rectangular shape (see fig. 1). Also, Kensey et al. disclose a tissue puncture closure assembly including an insertion sheath (34) and a carrier tube (32).

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8. Claims 31, 45, and 46 are rejected under 35 U.S.C. 102(e) as being anticipated by Akerfeldt et al. (6,508,828). Akerfeldt et al. disclose, in figures 1 and 6-18, a tissue puncture closure device or assembly having a carrier tube (24) or insertion sheath, a filament (12), an anchor (2), a sealing plug (18) that is folded at least once or is in a V-shape when open (as seen fig. 18, and closed as seen in fig. 1).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rousseau (6,425,924) in view of Himpens et al. (5,397,331). Rousseau discloses the invention substantially as claimed. Rousseau discloses, in figures 1-4, a tissue puncture closure device having a filament (22), an anchor (14) or internal component, a sealing plug (another element 14) with a high surface-area-to volume ratio or first external component, where the sealing plug comprises at least two folds or at least two

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S-folds, and where the sealing plug comprises two cross members having a weave pattern. However, Rousseau does not disclose a carrier tube. Himpens et al. teach, at least in figures 6-8 and 10 and in col. 5, line 62 to col. 6, line 16; a carrier tube (23) for a closure device analogous to the device of Rousseau. Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Himpens et al., to include a carrier tube with the device of Rousseau. Such a tube would ease deployment of Rousseau's device through a body cavity for access to and repair of a hernia.

11. Claims 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schmieding (6,027,523). Schmieding discloses the invention substantially as claimed. Schmieding discloses an internal tissue puncture closure device including an anchor (50, 52, 54, or 56), a filament, and a sealing plug (42), where the sealing plug includes two cross members. However, Schmieding does not disclose that the filament extends through a plurality of holes in each of the two cross members. Nevertheless, Schmieding discloses a sealing plug (4) with a plurality of holes for receiving filaments (6, 36). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made, to include a plurality of holes in each of the two cross members. Such holes would allow convenient attachment of filaments to the sealing plug, while allowing at least two portions of a filament or two filaments to securely connect the sealing plug (and tissue) to the anchor.

12. Claims 37-40, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akerfeldt et al. (6,508,828). Akerfeldt et al. disclose the invention substantially as

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claimed. Akerfeldt et al. disclose, in figures 1 and 6-18, a tissue puncture closure device and a method of sealing an internal tissue puncture having a carrier tube (24) or insertion sheath, an anchor (2), a sealing plug (18) that is folded at least once or from a V-shape (fig. 18) into a substantially straight shape, and a filament (12). However, Akerfeldt et al. do not disclose that the sealing plug is folded so that one portion of the sealing plug is in contact with another portion of the sealing plug, when the closure device is in an undeployed configuration. Nevertheless, Akerfeldt et al. disclose, in figures 15 and 17, that the sealing plug is folded so that one portion of the sealing plug is in contact with another portion of the sealing plug when parts 41 and 42 are moved along filament (12). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made, to move parts 41 and 42 within the carrier tube (as shown in figures 8, 10, and 11), so that the sealing plug is folded so that one portion of the sealing plug is in contact with another portion of the sealing plug (while the closure device is in an undeployed configuration within the carrier tube). Such a narrowed configuration of the sealing plug would ease its deployment through a puncture in a vessel.

Allowable Subject Matter

13. Claims 23, 24, 26, 27, 29, 30, 32, and 44 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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14. Claims 5-14 and 36 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

15. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination discloses a tissue puncture closure device having, inter alia, a carrier tube, a filament, an anchor, and a sealing plug or first external component, and a second external component folded and engaged with the first external component, where the sealing plug comprises an X-shape in cross-section or two components folded into a generally U-shape and interconnected with each other, where the external component is collagen sponge folded into legs of a general V-shaped folded along a centerline; where the filament alternately extends through holes in two cross members of the sealing plug in a spiral pattern, where first and second halves of a flexible sealing plug are folded latitudinally adjacent to one another, where the device includes a second external component folded and engaged with a first external component, and where the sealing plug is tri-folded into an S-shape as seen from an end view while the plug is disposed in the carrier tube.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Response to Amendment

16. Applicant's arguments filed on August 7, 2006 have been fully considered but they are not persuasive: See the restated and new grounds of rejection above.

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With respect to arguments regarding the rejection under 35 U.S.C. 112: The "open rectangle" has not been defined *within the claim*, although clarification was made in the arguments and the text of specification. The claims should set forth the conditions for establishment of an "open rectangle" as compared to, for example, a closed rectangle or a folded structure. That is, although "open" has been defined in the specification, the term is broad enough to include other definitions when applied in the claims.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Gerke et al. (6,652,560) teach a plug with an X-shaped cross-section.

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18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Julian W. Woo
Primary Examiner

October 23, 2006